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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,004	03/06/2000	John Paul Maye	046436-5016	7731
21874	7590	11/09/2010		
EDWARDS ANGELL PALMER & DODGE LLP			EXAMINER	
P.O. BOX 55874			STULI, VERA	
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1781	
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			11/09/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/520,004	MAYE ET AL.
	Examiner VERA STULII	Art Unit 1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

1) Responsive to communication(s) filed on 02 September 2010.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2-18,20 and 21 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 2-18,20 and 21 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449)  
 Paper No(s)/Mail Date \_\_\_\_\_ 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- i) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41 and 43-47 of copending Application No. 11/473,533.
- ii) Claims 2-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-40 of copending Application No. 10/361976.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the addition of various types of hops acid solutions to fermentation media, including brewing and production of alcohol

spirits, in order to avoid contamination by undesired microorganisms. Further, the recited method steps do not add patentable distinction between the two.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 2-6, 8-11, 14-15 and 20-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST) essentially for the same reasons as stated in the Non-Final Office action mailed 03/30/2010.

**Claims 7 and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST) as applied to claims 2-6, 8-11, 14-15 and 20-21 above and further in view of Simpson (Synergism Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast) essentially for the same reasons as stated in the Non-Final Office action mailed 03/30/2010.

**Claims 12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Todd, Jr. et al. (US 5,082,975) in view of ALCOHOL DISTILLERS HANDBOOK, Righelato et al. (Anaerobic Fermentation: Alcohol Production [and Discussion]) and Richards et al. (OXYGEN CONSUMPTION AND CARBON DIOXIDE PRODUCTION DURING THE GROWTH OF YEAST) and Simpson (Synergism Between Hop Resins and Phosphoric Acid And Its Relevance To The Acid Washing of Yeast) and further in view of Todd, Jr. (US 4,002,863) essentially for the same reasons as stated in the Non-Final Office action mailed 03/30/2010.

***Response to Arguments***

Applicant's arguments filed 09/02/2010 have been fully considered but they are not persuasive.

In response to applicants' arguments regarding Todd, Jr. et al. (US 5,082,975) herein after Todd (pages 7 and 8 of the Reply to the Non-Final Office action mailed 03/30/2010), it is noted that Todd, Jr. et al. disclose synthesis of hydrogenated purified beta acid (hexahydrolupulone) and its use as a selective inhibitor of cell growth (Col. 2 lines 33-41, Col. 3 lines 7-20), "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein" (Col. 3 lines 7-8), "the inhibition of a Lactobacillus microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a Lactobacillus-inhibiting amount of hexahydrolupulone thereto" (Col. 3 lines 9-11). Todd, Jr. et al. disclose:

- hydrogenated purified beta acid (hexahydrolupulone) and its use as a selective inhibitor of cell growth (Col. 2 lines 33-41, Col. 3 lines 7-20);
- “the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein” (Col. 3 lines 7-8);
- “the inhibition of a Lactobacillus microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a Lactobacillus-inhibiting amount of hexahydrolupulone thereto” (Col. 3 lines 9-11).
- “the selective inhibition of one microorganism in the presence of another by the application of an amount of hexahydrolupulone which is inhibitory as to the one microorganism but not the other” (Col. 3 lines 16-19).

As stated above, Since Todd, Jr. et al disclose use of hexahydrolupulone to inhibit the growth of Lactobacillus in the brewhouse (alcohol production) and in other fermentation processes (Col. 8 lines 8-12), and since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production, one of the ordinary skill in the art would have been motivated to modify disclosure of Todd, Jr. et al and to use hop acids extract in ethanol (alcohol) production at any stage of the ethanol production where inhibiting of bacteria is required. One of ordinary skill in the art would have been motivated to use hop acids solutions in production of ethanol to inhibit growth of Lactic acid bacteria, since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production for antibacterial purposes. One of ordinary skill in the art would have been motivated to add hop acids solutions to the

yeast growing tank, and then to transfer the mixture to the fermentation vessel, since Todd, Jr. et al. disclose "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of *Lactobacillus* therein" (Col. 3 lines 7-8). The specific conditions of yeast growing (such as addition of air) would not impart any patentable distinction.

In response to the aerobic/anaerobic conditions arguments on page 7 of the Reply, it is noted that Todd is not relied upon as a teaching of aerobic/anaerobic conditions, and there is no requirement in Todd for these conditions. The aerobic/anaerobic conditions have nothing to do with the addition of hexahydrolupulone to a yeast culture to inhibit the growth of *Lactobacillus*. Further in response to the argument, regarding the growth of yeast under aerobic conditions, it is noted that it was well known in the art that oxygen is one of the required components of the yeast growing media, and that aerobic growth of yeast is a standard practice in the art. As stated in the Non-Final Office action mailed 03/30/2010, Righelato et al. discloses that "Fermentation, the anaerobic catabolism of carbohydrates, proceeds by the oxidation of sugars to pyruvic acid, which process yields the cell energy and produces reduced nucleotides and a number of products that are potentially useful to man (table 1). Ethanol is the most widely known of these, as an industrial product, made by the reductive decarboxylation of pyruvate. From each mole of hexose, 2 mol of ethanol are generated conserving over 90 % of the calorific value of the sugar in the product". Richards et al discloses consumption of oxygen during the yeast growth. Therefore, one of ordinary skill in the art would have been motivated to modify Todd and to employ

conventional conditions for alcohol fermentation and yeast growth such as aerobic for yeast growth and anaerobic for fermentation.

In response to Applicant's arguments on page 8 of the Reply, it is noted that the claimed invention is directed towards "an improved process for inhibiting bacterial growth in an aqueous process medium comprising adding a hop acid". Applicant's invention is not directed to the method of growing yeast. Todd is relied upon as a teaching of inhibiting bacterial growth in an aqueous process medium comprising adding a hop acid, "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of *Lactobacillus* therein" (Col. 3 lines 7-8); "the inhibition of a *Lactobacillus* microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a *Lactobacillus*-inhibiting amount of hexahydrolupulone thereto" (Col. 3 lines 9-11). Since Todd, Jr. et al disclose use of hexahydrolupulone to inhibit the growth of *Lactobacillus* in the brewhouse (alcohol production) and in other fermentation processes (Col. 8 lines 8-12), and since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production, one of the ordinary skill in the art would have been motivated to modify disclosure of Todd, Jr. et al and to use hop acids extract in ethanol (alcohol) production at any stage of the ethanol production where inhibiting of bacteria is required. One of ordinary skill in the art would have been motivated to use hop acids solutions in production of ethanol to inhibit growth of Lactic acid bacteria, since it was well known in the art to use hop acids (resins) extracts for preparation of yeast fermentation mashes in alcohol (ethanol) production for antibacterial purposes. One of ordinary skill in the art

would have been motivated to add hop acids solutions to the yeast growing tank, and then to transfer the mixture to the fermentation vessel, since Todd, Jr. et al. disclose "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of *Lactobacillus* therein" (Col. 3 lines 7-8).

In response to Applicants arguments regarding the ALCOHOL DISTILLERS HANDBOOK reference, it is noted that this reference is relied upon as a teaching of the fact that "[h]ops extract is occasionally used with water for preparation of yeast mashes because it contains resins and is believed to inhibit the growth of microorganisms" (p. 57). It is also noted that the term "yeast mash" suggests presence of yeast. Even if the preliminary yeast mash does not contain yeast at the moment of addition of hop acids/extracts, it is intended for the so called "yeasting", i.e. addition of yeast. Thus, such "yeast mash" containing hop extracts/acids is contacted with yeast. Further in response to Applicants arguments regarding the ALCOHOL DISTILLERS HANDBOOK reference, it is noted that the reference is not relied upon as a teaching of aqueous alkaline solution of hop acids. Todd is relied upon as a teaching of aqueous alkaline solution of hop acids.

In response to applicant's arguments against the references individually page 10 of the Reply), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Righelato et al and Richards et al are relied upon as a

teaching of conventional conditions for alcohol fermentation and yeast growth such as aerobic for yeast growth and anaerobic for fermentation.

In response to applicant's arguments on page 11 of the Reply, Applicants are referred to the Response to arguments as stated above.

In response to Applicant's arguments regarding declaration under 37 CFR 1.132 (page 12 of the Reply), it is noted that the declaration has been addressed in the Non-Final Office action mailed 12/11/2008. As stated in the Non-Final Office action mailed 12/11/2008, declaration states that one of ordinary skill in this field would not have expected the use of hop acids in the manner claimed in the above-identified application to have any appreciable effects on fuel ethanol production (page 2 of declaration). This argument is not deemed persuasive for the reasons of record stated in the previous Office actions. In regard to this argument it is noted that, Todd, Jr. et al. (US Patent 5,082,975) use of hydrogenated purified beta acid (hexahydrolupulone) as a selective inhibitor of cell growth (Col. 2 lines 33-41, Col. 3 lines 7-20). Todd, Jr. et al. disclose "the addition of hexahydrolupulone to a yeast culture to inhibit the growth of Lactobacillus therein" (Col. 3 lines 7-8). Todd, Jr. et al. disclose "the inhibition of a Lactobacillus microorganism in the presence of yeast without inhibiting growth of the yeast by the application of a Lactobacillus-inhibiting amount of hexahydrolupulone thereto" (Col. 3 lines 9-11). Todd, Jr. et al. disclose that "[m]oreover, its use in inhibiting Lactobacillus infections in the brewhouse will become immediately apparent to one skilled in the brewing art. Other useful applications in fermentation processes, as well as pharmaceutical applications, will also be apparent to one skilled in the art" (Col. 8 lines

3-13). ALCOHOL DISTILLERS HANDBOOK is a further evidence of the fact that "Hops extract is occasionally used with water for preparation of yeast mashes because it contains resins and is believed to inhibit the growth of microorganisms" (p. 57). Therefore, taking in consideration the combination of references and art as a whole, Applicants arguments are not deemed persuasive.

In response to Applicant's argument regarding Double patenting rejections, it is noted that a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Since Applicant submitted none of the above, double patenting rejections are maintained for the reasons of record.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VERA STULII whose telephone number is (571)272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vera Stulii/  
Examiner, Art Unit 1781

/Keith D. Hendricks/  
Supervisory Patent Examiner, Art Unit 1781